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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,028	02/16/2006	David L Reynolds	12916-86	3363
45971	7590	12/26/2007		
ERIC FINCHAM 316 KNOWLTON ROAD LAC BROME, QC J0E 1VO CANADA			EXAMINER HAND, MELANIE JO	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,028	Applicant(s) REYNOLDS, DAVID L	
	Examiner Melanie J. Hand	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) ,
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/26/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority benefit of copending provisional Application No. 60/424,713, filed on November 8, 2002.
2. Acknowledgment is made of applicant's claim for priority benefit of PCT/CA03/01713 under 35 U.S.C. 371, filed on November 7, 2003.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on August 26, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5-7 and 9-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Aneas (U.S. Patent No. 6,070,623).

With respect to **claim 1**: Aneas teaches an assembly for transferring a liquid between a vial and a syringe, comprising: a) a housing in the form of means 22 for locking the assembly on vial 2 having a central portion, the housing 22 being open at one end and having a vial socket in the

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form of stopping members 18 at the other opposite end adapted to receive and retain a vial 2 having a penetrable closure 3 (Fig. 1); b) a sleeve in the form of skirt 12 located within the central portion of the housing 22, the sleeve 12 having a first portion, a second portion adjacent the first portion, and a shoulder between the first portion and the second portion; c) a protractible luer adaptor in the form of faucet 6 having a female luer lock component with a central hub in the form of perforating apparatus 5 having a first axial end and a second axial end, the first axial end having mounted thereon a piercing member 5a having a bore and a tip having an opening and the second axial end in the form of collar 5c having an engaging member for releasably engaging a syringe (second receptacle taught by Aneas). As can be seen in Fig. 1, the piercing member 5a, the central hub 5, and the engaging member 5c are integral and thus are necessarily in fluid communication with one another; d) the protractible luer adaptor 6 being longitudinally slidable within the sleeve 12 between a retracted position where the tip of the piercing member 5a is substantially contained within the central portion of the housing (Fig. 2) and an advanced position where the tip of the hollow piercing member 5a extends into the vial socket (Fig. 3). (whole document)

With respect to **claim 5**: The assembly of Aneas further comprises a syringe socket at the open end of the housing 22 for receiving a syringe.

With respect to **claim 6**: Aneas teaches an assembly further comprising a retaining member 14 in the vial socket for retaining a vial 2 within the vial socket.

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With respect to **claim 7**: The retaining member 14 comprises an annular ridge on the interior surface of the vial socket, the annular ridge having a smaller diameter than the diameter of the vial socket. (Fig. 1)

With respect to **claim 9**: The assembly of Aneas further comprising a shoulder in the form of stopping members 18 between the vial socket and the central portion of the housing 22 to limit the degree of insertion of a vial 2 in the housing 22.

With respect to **claim 10**: The housing 22 includes at least one rib on an interior surface of the housing 22, specifically the inner surface of skirt 12. With respect to the limitation "to limit the degree of insertion of a vial in the housing", the ribs taught by Aneas are inherently and necessarily capable of limiting the degree of insertion of a vial in the housing by obstructing the vial's passage.

With respect to **claim 11**: The interior surface of the first portion includes a detent adjacent the open end of the syringe engaging and retaining the protractible luer adaptor 6 in the retracted position. (Fig. 2)

With respect to **claim 12**: The protractible luer adaptor 6 includes a flange adjacent the second end and the detent is configured to receive the flange therein. (Fig. 1)

With respect to **claim 13**: The assembly further comprises a plurality of longitudinal ribs on an interior surface of the second portion of the sleeve 12 that matingly engage a plurality of longitudinal ribs on the central hub toward the plunger 15 of the protractible luer adaptor 6 to

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prevent rotation of the protractible luer adaptor with respect to the housing during operation.

With respect to **claim 14**: The protractible luer adaptor 6 includes a flange adjacent the second end, the flange abutting the shoulder 15b between the first portion and the second portion while in the advanced position to limit the advancement of the tip of the piercing member 5a into the vial socket.

With respect to **claim 15**: The diameter of the flange is substantially equal to the inner diameter of a first portion of the sleeve 10 to provide a fluid seal therewith when the protractible luer adaptor 6 is in the advanced position.

With respect to **claim 16**: The assembly of Aneas further comprises at least one protrusion on an exterior surface of the protractible luer adaptor 6, the at least one protrusion having a bottom edge and a side edge, the bottom edge 15 abutting the top surface of the second portion of the sleeve while in the advanced position to prevent the protractible luer adaptor from being removed from the sleeve.

With respect to **claim 17**: Aneas teaches an assembly for use with a syringe having a body 22, a neck end 12, and a hollow cannula 5a, the assembly comprising a needle having a tip with a first opening, a base with a second opening, and a central bore 9 extending between the first and second openings, the base is a separate slidable structural piece from the syringe and is thus adapted to be releasably mounted on the neck end of the syringe via luer adapter 6 connected thereto.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas ('623).

With respect to **claim 2**: The assembly of Aneas further comprises a venting needle assembly (collectively 5a,9,10) mounted on the first axial end of the protractible luer adaptor 6 to provide a passageway for gas to flow between a vial 2 retained in the vial socket and the assembly when the protractible luer 6 is in the 25 advanced position.

Aneas does not teach that the venting needle assembly is releasably mounted on the first axial end of the protractible luer adapter 6. However, since the luer adapter mates with the luer lock component of a syringe, it would be obvious to one of ordinary skill in the art to modify the device of Aneas such that the venting assembly 5a,9,10 is releasably mounted to the luer

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adapter to allow the luer adapter to be more accessible to a user to ensure the syringe contents are secured and do not leak.

With respect to **claim 3**: The venting needle assembly comprises a needle 5a having a bore 10 and a tip with a first opening, and a base having a second opening, the first and second openings being in fluid communication with one another as can be seen in Fig. 1.

With respect to **claim 4**: Aneas does not explicitly teach that the diameter of the bore 10 of the venting needle is smaller than the diameter of the bore 9 of the piercing member 5a. However, since the bore 10 merely assists bore 9 in establishing fluid communication between filter 7 and vial 2, it would be obvious to one of ordinary skill in the art to modify the device of Aneas such that the bore 10 has a smaller diameter since substantially all of the negative pressure imposed when the plunger 15 is pulled back will be borne by bore 9 which would require a larger diameter to handle the negative pressure as well as fluid flow pressure.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas ('623) in view of Reynolds (U.S. Patent No. 6,149,623).

With respect to **claim 8**: Aneas does not teach that the retaining member comprises a plurality of latches provided in the vial socket. Reynolds teaches a device for delivering pharmaceuticals from a vial to a syringe having a retaining member as claimed comprising latches 56. Reynolds teaches that the latches engage and retains shoulder 42 abutting hollow needle 41, similar to needle 5a of Aneas, in place to ensure effective delivery of the pharmaceutical, therefore it

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would be obvious to one of ordinary skill in the art to modify the device of Aneas such that the retaining member 14 has latches as taught by Reynolds to retain both the vial and the perforating member 5a in place during delivery of fluid. (Col. 5, lines 41-44, Col. 7, lines 57-65, Col. 8, lines 51-61)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

December 19, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

